K021649

SEP 19 2002

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Binax NOW® FLU A Test

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter:

Binax, Inc.
217 Read Street
Portland, Maine 04103

Attention: Anne Jepson
(207) 772-3988 (Office)
(207) 871-5751 (FAX)
ajepson@binax.com (email)

Trade Name: Binax NOW® Flu A Test

Common Name: Flu A ICT, NOW® Flu A test, NOW® Influenza A, Influenza A ICT

Classification Name: Antigens, CF (Including CF Control), Influenza virus A, B, C (per 21 CFR 866.3330)

Predicate Device: Quidel QuickVue® Influenza Test, 510(k) number K991633

Device Description: The Binax NOW® Flu A Test is an immunochromatographic membrane assay used to detect influenza A nucleoprotein antigen in nasal wash and nasopharyngeal swab specimens. A test strip, containing gold-conjugated and immobilized anti-influenza A antibodies, is mounted on the right side of a cardboard, book-shaped hinged test device. Swab specimens require a sample preparation step, in which the sample is eluted off the swab into a saline solution. The nasal wash sample does not require any preparation. The sample to be tested is added to a pad at the top of the test strip, and the test device is closed. Influenza A antigen present in the sample reacts to bind anti-influenza A conjugated antibody. The resulting antigen-conjugate complexes are captured by immobilized anti-influenza A antibody, forming the Sample Line. Immobilized

Control Line antibody, which appears as a blue line in an untested device, captures a visualizing conjugate, forming a pink Control Line. The sample is contained, and results are available within 15 minutes.

Intended Use:

The Binax NOW® Flu A Test is an *in vitro* rapid immunochromatographic assay for the qualitative detection of influenza A nucleoprotein antigen in nasal wash and nasopharyngeal swab specimens from symptomatic patients. It is intended to aid in the rapid diagnosis of influenza A infections. Negative test results should be confirmed by cell culture.

Technological Characteristics:

Both the Binax NOW® Flu A Test and the Quidel QuickVue® Influenza Test are simple rapid immunochromatographic tests with a visual result interpretation. Both employ antibodies conjugated to visualizing particles and an antibody striped membrane to capture and visualize influenza A antigen. The Quidel QuickVue® Test also detects influenza B antigen.

Performance Summary:

The Binax NOW® Flu A Test is substantially equivalent to the predicate device, the Quidel QuickVue® Influenza Test (K991633), for the detection of influenza A antigen. The performance of the Binax NOW® Flu A Test was verified using freshly collected and characterized nasal wash and nasopharyngeal swab specimens. Refer to attached **PERFORMANCE CHARACTERISTICS.**

Signed_____ Date _____

Karen Hickey

Vice President, Regulatory Affairs

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS (Continued)

PERFORMANCE CHARACTERISTICS
BINAX NOW® FLU A TEST

Analytic Reactivity:
Although the specific influenza A strains causing infection in humans can vary year to year, all contain the conserved nucleoprotein targeted by the Binax NOW® test.[1] Six (6) ATCC traceable influenza A strains were assayed in the Binax NOW® test at concentrations ranging from 10^3 to 10^5 $TCID_{50}$/ml. One hundred percent (100%) were positive, indicating that the Binax NOW® test detects all influenza A strains.

Analytic Specificity (Cross-Reactivity):
To demonstrate the immunologic specificity of the Binax NOW® test, 42 potential cross-reactants were tested in the Binax NOW® test. The cross-reactant panel included bacteria and viruses that may be present in respiratory specimens. Bacteria tested at concentrations greater than 1 x 10^8 organisms/ml and viruses tested at concentrations greater than 1 x 10^5 $TCID_{50}$/ml did not cross-react in the Binax NOW® Test.

Clinical Sensitivity and Specificity:
The Binax NOW® Flu A Test was evaluated in prospective clinical studies.

In a multi-site prospective study, 191 nasal wash specimens and 182 nasopharyngeal swab specimens collected from patients presenting with influenza-like symptoms were tested in the NOW® test and in culture. NOW® test performance versus viral cell culture, calculated using standard methods, was as follows:

Nasal wash specimens:	82% sensitivity 94% specificity 91% overall accuracy
Nasopharyngeal swab specimens:	78% sensitivity 92% specificity 89% overall accuracy

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS (Continued)

PERFORMANCE CHARACTERISTICS
BINAX NOW® FLU A TEST

Ninety-five percent (95%) confidence intervals are listed below.

Nasal Wash Specimens:

		Viral Culture +	-
NOW® Result	+	40	9
	-	9	133

Sensitivity	=	82%	(69% - 90%)
Specificity	=	94%	(89% - 97%)
Accuracy	=	91%	(86% - 94%)

Nasopharyngeal Swab Specimens:

		Viral Culture +	-
NOW® Result	+	29	12
	-	8	133

Sensitivity	=	78%	(62% - 88%)
Specificity	=	92%	(86% - 95%)
Accuracy	=	89%	(84% - 93%)

Interfering Substances:

The Binax NOW® test was found not to cross-react with 19 substances that may be artificially introduced into the nasal cavity or nasopharynx or that are naturally present in respiratory specimens. These 19 potentially interfering substances were diluted to appropriate concentrations in a saline/BSA solution and tested in the Binax NOW® Test. A portion of each of these solutions was also spiked with the limit of detection (LOD) level of a viable influenza A strain (See LOD Testing, Section 9) before testing in the Binax NOW® Test. All negative (no virus) and positive (spiked with LOD virus) samples generated expected results in the Binax NOW® Test.

Reproducibility:

A blind study of the Binax NOW® test was conducted at 3 separate sites using a panel of coded specimens containing negative, low positive, and moderate positive controls. Participants performed

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS (Continued)

PERFORMANCE CHARACTERISTICS
BINAX NOW® FLU A TEST

testing on 3 different days. One hundred percent (100%) of the 234 samples tested were correctly interpreted.

Quality Control:

The ability of the Binax NOW® Test procedural control to indicate test failure was evaluated when 3 operators each ran 20 kit controls in a panel of 20 devices, 9 of which had been rendered inoperative. The number of defective devices and the defect itself were not apparent to the operator. One hundred percent (100%)of the 60 devices were correctly interpreted as positive, negative, or invalid.

Preliminary Stability:

Preliminary stability studies of the Binax NOW® Flu A Test and kit controls are ongoing. Test results are consistent with other Binax 510(k) cleared ICT products. A minimum shelf life of one year is anticipated.

References:

1 Dowdle, W.R, Kendal, A.P., and Noble, G.R. 1980. Influenza Virus, p 836-884. Manual of Clinical Microbiology, 3rd edition, In Lennette, et. Al (ed.). American Society for Microbiology, Washington, D.C

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Anne Jepson
Manager, Technical Support and Services
Binax, Inc.
217 Read Street
Portland, ME 04103

SEP 19 2002

Re: k021649
Trade/Device Name: Binax Now® Flu A Test
Regulation Number: 21 CFR 866.3330
Regulation Name: Influenza Virus Serological Reagents
Regulatory Class: Class I
Product Code: GNX
Dated: July 31, 2002
Received: August 1, 2002

Dear Ms. Jepson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

APPENDIX B

INDICATIONS FOR USE FORM

510(k) Number (if known): K021649

Device Name: Binax NOW® Flu A Test

Indications For Use:

The Binax NOW® Flu A Test is an *in vitro* rapid immunochromatographic assay for the qualitative detection of influenza A nucleoprotein antigen in nasal wash and nasopharyngeal swab specimens from symptomatic patients. It is intended to aid in the rapid diagnosis of influenza A infections. Negative test results should be confirmed by cell culture.

Woody Dubois

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K021649